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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,872

Applicant(s)

WAI-CHIU SO ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt for Extension of Time, Supplemental IDS, and Request for Reconsideration, received September 30, 2002 is acknowledged. Claims 1-24 are included in the prosecution of this application.

Response to Arguments

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Yu et al is directed to the use of hydroxy acids to enhance the therapeutic efficacy of cosmetic and pharmaceutical agents and does not even remotely address the problem which the present invention solves, namely increasing the minoxidil amounts while minimizing the amounts of propylene glycol, or other polyols. Applicant further argues that Yu et al clearly does not disclose or suggest the composition of claim 1 which specifically requires at least 5 % by weight of a piperdinopyrimidine derivative or a pharmaceutically acceptable salt thereof and propylene glycol, if present at all, in an amount of less than approximately 10 % by weight. These arguments are not found to be persuasive for the following reasons. Yu et al is directed to hydrophobic agents just as in instant case and Yu does teach minoxidil in Example 3. Although in this example the amount of propylene glycol is higher than the claimed amounts (15 % in the example vs. 10 % as the upper limit in instant claims), Yu et al suggest propylene glycol in amounts varying from 2 %, 7 % in Examples 18, 24 and 26-28 for other hydrophobic drugs. Therefore, it would have been obvious to one of ordinary skill in the art to use appropriate amounts of propylene glycol for minoxidil based on the suggestion and guidance provided by Yu. Furthermore,

Art Unit: 1616

instant amount reciting "of less than approximately 10 % by weight" refer only to instances when the co-solvent involves propylene glycol; instant claim 1 does not recite any amounts when the co-solvent is a polyhydric alcohol and Yu's teachings include glycerol in other examples dealing with other hydrophobic compounds.

With regard to lack of teachings of at least 5 % by weight of the active agent in Example 3 of Yu, the examiner points out that the amounts of the active agent depends upon various parameters such as the condition to be treated and severity of the disease. Therefore, this is a manipulatable parameter and it is well within the skill of an artisan in the art to vary the amounts of the active agents based on the suggestion by Yu that the active agent ranges from 0.01 % to 40 %. Although as applicant claims that this is a broad statement, it is the examiner's position that it would have been obvious to one of ordinary skill in the art to manipulate the amounts with the guidance provided by Yu through several examples for other hydrophobic active agents. One of ordinary skill in the art would be motivated further to use higher amounts of minoxidil since the secondary reference of Kasting shows that compositions containing higher amounts of minoxidil are known in the art.

Applicant's arguments that Kasting et al attempt to enhance penetration of minoxidil by adding a lipid component to a formulation containing a diol, such as propylene glycol are not found to be persuasive since instant 'comprising' does not exclude the lipid component of Kasting et al. With regard to applicant's arguments that claim 21 is directed to a method for the treatment of hair loss and related conditions, the

Art Unit: 1616

examiner points out that Example 3 of Yu clearly teaches that the composition is for preventing the hair loss.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (5571841) by itself or in combination with Kasting et al (5041439) or vice-versa.

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines1-3). The composition is applied to the scalp to treat hair loss (Note example 3).

Yu et al does not provide an example with instant amount of minoxidil.

Kasting et al teaches a minoxidil acid salt made from an acid such as acetic or lactic acid (col. 6, lines 44-53). Kasting teaches using 12% active, 54% 1,2 6-hexanetriol, oleyl alcohol, and 30% ethanol (Note composition XIV). The reference teaches several ranges in the examples. Kasting teaches the amount of active also

Art Unit: 1616

depends on factors such as the severity of the condition, the cause of the condition, the specific active used, etc. (col.7, lines 5-15).

Although, Yu does not provide a specific example, it is deemed obvious to one of ordinary skill in the art, in the absence of showing unexpected results, to manipulate the conditions to obtain the best possible results since Yu et al provides the general guidance of the hair treating composition. One would be motivated to change the concentration of minoxidil depending on the severity of the condition. Further, Kasting et al teaches a hair loss composition and manipulating the solvent system and active agent to obtain a therapeutic composition without irritation.

Response to Arguments

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Yu et al and Kasting et al have been addressed above. Applicant's argues that Uchikawa et al is directed to hair revitalizing tonics containing amine oxide and that the reference is specifically relied upon as teaching the use of benzyl alcohol as a solvent and certain ratios of water/ethanol mixtures. It is argued because of the deficiencies of Yu et al and Kasting et al, the addition of benzyl alcohol or the water/ethanol mixtures of Uchikawa to the formulations of Yu et al and/or Kasting et al still would not achieve or suggest the specific claimed formulation. This argument is not found to be persuasive since the apparent deficiencies of Yu and Kasting as argued by applicant have been addressed above and the motivation to add benzyl alcohol has already been set forth by the examiner.

Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (5571841) by itself or in combination with Kasting et al (5041439) or vice-versa, in further view of Uchikawa et al (5156836).

As set forth above, Yu and Kasting teach a hair loss composition containing a piperidinopyrimidine derivative and a solvent system.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34). Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to use benzyl alcohol or ethanol in the solvent system since Uchikawa et al teaches the use of either alcohols in the hair tonic.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


Art Unit: 1616


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

December 9, 2002


MICHAEL G. HARTLEY
PRIMARY EXAMINER